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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/030,735 | 01/09/2002 | David D. Roberts | 15280-3971US | 8279 |

7590 01/30/2004

Kenneth A Weber
Townsend & Townsend & Crew
8th Floor
Two Embarcadero Center
San Francisco, CA 94111-3834

| EXAMINER | |
|---|---|
| HADDAD, MAHER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/030,735 | ROBERTS ET AL. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 August 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

1. Applicant's amendment, filed on 8/09/02, is acknowledged.

2. Claims 1-45 are pending.

### *Election/Restrictions*

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-10 and 13-14, drawn to a peptide comprising the sequence R1-X1-X2-X3-X4-R2 and compositions thereof.

II. Claims 11-12 and 17, drawn to a peptide-substrate combination comprising a substrate suitable for cell growth and a peptide of 4-12 amino acids attached to said substrate, said peptide comprising the sequence R1-X1-X2-X3-X4-R2.

III. Claims 15-16, drawn to a peptide conjugate comprising a peptide and a water soluble polymer, said peptide comprising the sequence R1-X1-X2-X3-X4-R2.

IV. Claim 18, drawn to a vascular graft comprising the peptide-substrate combination comprising a substrate suitable for cell growth and a peptide of 4-12 amino acids attached to said substrate, said peptide comprising the sequence R1-X1-X2-X3-X4-R2.

V. Claim 19, drawn to an artificial blood vessel comprising the peptide-substrate combination comprising a substrate suitable for cell growth and a peptide of 4-12 amino acids attached to said substrate, said peptide comprising the sequence R1-X1-X2-X3-X4-R2.

VI. Claims 20-25, drawn to a method of inhibiting adhesion of a cell expressing $\alpha 3\beta 1$ integrin to an extracellular matrix comprising contacting a cell with a peptide comprising the sequence R1-X1-X2-X3-X4-R2.

VII. Claims 26-28, drawn to a method of inhibiting $\alpha 3\beta 1$ integrin-mediated cell motility comprising contacting a cell with a peptide comprising the sequence R1-X1-X2-X3-X4-R2.

VIII. Claim 29, drawn to a method of inhibiting proliferation of endothelial cells, comprising contacting said cells with a peptide comprising the sequence R1-X1-X2-X3-X4-R2.

IX. Claim 30, drawn to a method of inhibiting proliferation of small cell lung carcinoma, comprising contacting said cell with a peptide of 4-6 amino acids comprising the sequence R1-X1-X2-X3-X4-R2.

X. Claims 31-33, drawn to a method of promoting the proliferation of endothelial cell *in vitro*, comprising contacting said cells with a peptide-peptide-substrate combination comprising the sequence R1-X1-X2-X3-X4-R2.

XI. Claims 31 and 33-36, drawn to a method of promoting the proliferation of endothelial cell *in vivo*, comprising contacting said cells with a peptide-peptide-substrate combination comprising the sequence R1-X1-X2-X3-X4-R2.

XII. Claims 38, 39 and 43, drawn to a method of treating an angiogenesis-mediated disease in animal comprising administering to the animal an effective amount of a peptide comprising the sequence R1-X1-X2-X3-X4-R2 wherein the angiogenesis-mediated disease is a diabetic retinopathy.

XIII. Claims 38, 39 and 43, drawn to a method of treating an angiogenesis-mediated disease in animal comprising administering to the animal an effective amount of a peptide comprising the sequence R1-X1-X2-X3-X4-R2 wherein the angiogenesis-mediated disease is a retinopathy of prematurity.

XIV. Claims 38, 39 and 43, drawn to a method of treating an angiogenesis-mediated disease in animal comprising administering to the animal an effective amount of a peptide comprising the sequence R1-X1-X2-X3-X4-R2 wherein the angiogenesis-mediated disease is rheumatoid arthritis.

XV. Claims 38, 39 and 43, drawn to a method of treating an angiogenesis-mediated disease in animal comprising administering to the animal an effective amount of a peptide comprising the sequence R1-X1-X2-X3-X4-R2 wherein the angiogenesis-mediated disease is a macular degeneration.

XVI. Claims 38, 39 and 43, drawn to a method of treating an angiogenesis-mediated disease in animal comprising administering to the animal an effective amount of a peptide comprising the sequence R1-X1-X2-X3-X4-R2 wherein the angiogenesis-mediated disease is an atherosclerosis plaque.

XVII. Claims 43-45, drawn to a method of treating an angiogenesis-mediated disease in animal comprising administering to the animal an effective amount of a peptide comprising the sequence R1-X1-X2-X3-X4-R2 wherein the angiogenesis-mediated disease is a cancer.

Claim 37 is a linking claim for Groups XII-XVII and will be examined along the elected invention of any one of Groups XII-XVII.

5. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of claims 1, 2 6-9, 13, 17 was found to have no special technical feature that defined the contribution over the prior art of Miles *et al* (J Biol. Chem. 269:30939-30945, 1994, IDS document) (see entire document).

Miles *et al* teach peptides comprising the sequence DLRL (X1-X2-X3-X4) and one peptide containing all D amino acids (see Figure 1, Tables I and II in particular). The peptides are 14 amino acids in length, R1 is between 1-5 amino acids and R2 is between 1-3 (The term "comprising" is an open ended. It would open up the peptide to include other undisclosed amino acids either or both N-terminal or C-terminal).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If anyone of Groups I-XVII is elected, applicant is required to elect a specific peptide sequence such as the one recited in claims 4 and 10, **or** (a single specific R1 sequence such as the one recited in claim 3, a single X1-X2-X3-X4 sequence such as the one recited in claim 5 and a single specific R2 sequence). These peptides are distinct species because they differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

B. If anyone of Groups XI-XVI is elected, applicant is required to elect a animal such as the one recited in claims 36 and 39. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, and represent patentably distinct subject matter.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
January 26, 2004

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/26/04